IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL LLC, Plaintiff, vs. TARO PHARMACEUTICAL INDUSTRIES LTD, Defendant.	**1:17-CV-663-JFB-SRF** **MEMORANDUM AND ORDER**

This matter is before the Court on the parties' motions in limine, (D.I. 133-1, Ex. 13 and D.I. 133-2, Ex. 14). This case arises out of the Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271(e). Defendant Taro Pharmaceutical Industries, LTD, a manufacturer of generic drugs, is seeking the approval of the United States Food and Drug Administration ("FDA") to sell a generic version of plaintiff Almirall LLC's ("Almirall") Aczone® 7.5% (dapsone) Gel product ("Aczone®"). On or around February 13, 2017, TARO submitted an abbreviated new drug application ("ANDA") No. 210191 to the FDA.[1] Almirall alleges approval of the application would induce infringement of U.S. Patent No. 9,517,219 ("the '219 patent") under the doctrine of equivalents and attempts to block approval of Taro's product by the FDA. ACZONE® was approved for marketing by the FDA in Allergan's New Drug Application ("NDA") No. 207154. Almirall is Allergan's successor in interest. ACZONE® Gel, 7.5% contains dapsone as its active

[1] By way of explanation, ANDAs are typically used by generic companies to obtain approval to market a generic version of an existing drug. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1350 (Fed. Cir. 2012). Unlike a new drug application ("NDA"), an ANDA applicant is not required to submit the same extensive clinical studies typically needed to prove the drug's safety and efficacy. *Id.* Instead, the ANDA applicant must submit studies to establish that its drug is bio-equivalent to the reference drug. *Id.* The ANDA must also include sufficient information to establish that the generic drug has the same active ingredients as the reference drug. *Id.*

pharmaceutical ingredient ("API"). Almirall alleges infringement of Claims 1, 2, 4, and 5 of the ’219 Patent under the doctrine of equivalents pursuant to 35 U.S.C. § 271(b) and (c). Specifically, Almirall alleges Taro's product includes a polymeric viscosity builder, or PVB,[2] equivalent to Sepineo P 600, the PVB used in Aczone®. Taro contends that its ANDA described product does not infringe the asserted claims of the ‘219 patent, and counterclaims for a declaratory judgment that the asserted claims are invalid. The ’219 patent is a method patent. The matter is set for trial on February 4, 2019.

A. Almirall LLC’s (“Almirall”) Motion in Limine (D.I. 133, Ex. 13)

1. Plaintiff’s Motion in Limine No. 1 to Preclude Testimony of Dr. Amiji Outside the Scope of His Expert Report

a. Parties’ Positions

Almirall moves to preclude Taro from eliciting expert opinion testimony from Dr. Amiji that is outside the scope of his expert report. Specifically, Almirall contends Dr. Amiji should not be allowed to testify regarding the amendment of claim 1 of U.S. Patent Application No. 14/082,955 (“the ’955 application”). The ’955 application is “parent application” to which the asserted ’219 patent claims priority. Almirall contends that in his report, Dr. Amiji’s opinion of prosecution estoppel relies exclusively on prosecution events relating to original claim 14, and also asserts that Taro now refers to the amendment of original claim 1 of the ’955 application in its statement of uncontested facts. *Id*. at 279. Almirall acknowledges, however, that Dr. Amiji recited the prosecution history of the ’955 application in a background section of his report, including events

[2] The term PVB has been construed to mean “a polymer or polymer-based thickening agent.” D.I. 87, Report and recommendation; D.I. 107, Memorandum and Order.

related to original claim 1. It argues that it has not had opportunity to respond to Dr. Amiji's opinions that rely on claim 1 prosecution history as the basis for prosecution history estoppel, nor to probe those opinions in deposition. It contends it would be prejudiced by presentation of his opinion as to claim 1 for the first time at trial.

Taro responds that, contrary to Almirall's assertion, Dr. Amiji explicitly referred to amendment of original claim 1 of the '955 application with a narrowing amendment to overcome a rejection over prior art compositions containing Carbomer. Further, it argues that even if Dr. Amiji did not expressly rely on the amendment to claim 1 in reaching his conclusion that Almirall's equivalents theory is barred by prosecution history estoppel, his anticipated testimony regarding the narrowing amendment to original claim 1 would be a permissible elaboration on the opinions set out in his expert report. Taro also contends that Almirall had sufficient notice of Dr. Amiji's anticipated testimony regarding the amendment to original claim 1 and its presumptive impact on Almirall's doctrine of equivalents theory by virtue of Dr. Amiji's references to the amendment of claim 1 in his report and Taro's motion for leave to file a motion for summary judgment, which espoused the same theory.[3] It also

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[3] The Court denied Almirall leave to file the summary judgment motion, stating:

> Taro's arguments in favor of early summary judgment focus in large part on statements made during prosecution of the application leading to the '219 patent, which allegedly limited the claimed polymeric viscosity builder ("PVB") to a single ingredient known as acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA") with the language "consisting of." (D.I. 22 at 3-5) However, the prosecution history reveals that the claim language was subsequently modified to a PVB "comprising" A/SA, which purportedly broadened the claim by permitting a PVB made of A/SA in combination with other ingredients. (D.I. 27, Exs. F-H) The purported equivalence of Taro's multi-component PVB and the claimed PVB in the '219 patent is the proper subject of fact and expert discovery, as well as claim construction.

(D.I. 39)

argues that Almirall's expert, Dr. Majella Lane, had an opportunity to attempt to rebut the presumption of prosecution history estoppel in her Reply Report and Almirall also had an opportunity to seek deposition testimony from Dr. Amiji regarding the amendment but chose not to do so. Taro contends that Almirall's failure to address the amendment in its expert reports or at deposition should not preclude Taro from eliciting expert opinion testimony from Dr. Amiji on the issue.

b. Law

Although the motion in limine is an important tool available to the trial judge to ensure the expeditious and evenhanded management of the trial proceedings, performing a gatekeeping function and sharpening the focus for later trial proceedings, some evidentiary submissions, cannot be evaluated accurately or sufficiently by the trial judge in such a procedural environment. *Jonasson v. Lutheran Child and Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997). A motion in limine is appropriate for "evidentiary submissions that clearly ought not be presented to the jury because they clearly would be inadmissible for any purpose." *Id.* In other instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate the impact of the evidence. *Id.*

Moreover, trial courts should be more reluctant to exclude evidence in a bench trial than a jury trial. *See First Am. State Bank v. Cont'l Ins. Co.,* 897 F.2d 319, 328 (8th Cir. 1990); *Builders Steel Co. v. Comm'r*, 179 F.2d 377, 379 (8th Cir. 1950). In bench trials, evidence should be admitted and then sifted when the district court makes its findings of fact and conclusions of law. *Fields Eng'g & Equip., Inc. v. Cargill, Inc.,* 651 F.2d 589, 594 (8th Cir. 1981). In a nonjury case, the trial court is presumed to consider

only the competent evidence. *First Am. State Bank*, 897 F.2d at 328. Where the court has assumed the role of fact-finder in a bench trial, "the better course" is to "hear the testimony, and continue to sustain objections when appropriate." *Easley v. Anheuser-Busch, Inc.,* 758 F.2d 251, 258 (8th Cir. 1985).

"Evidentiary rulings made by a trial court during motions in limine are preliminary and may change depending on what actually happens at trial." *Walzer v. St. Joseph State Hosp.*, 231 F.3d 1108, 1113 (8th Cir. 2000); *see also Leonard v. Stemtech Health Scis., Inc.*, 981 F. Supp. 2d 273, 276 (D. Del. 2013) (noting that evidentiary rulings, especially those that encompass broad classes of evidence, should generally be deferred until trial to allow for the resolution of questions of foundation, relevancy, and potential prejudice in proper context).

The Federal Rules of Civil Procedure require a testifying expert to prepare and sign a written report containing, inter alia, "a complete statement of all opinions the witness will express and the basis and reasons for them . . . at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(B)(i) & (a)(2)(D). Rule 26 also imposes a duty to "supplement or correct [an expert report] . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). "If a party fails to provide information or identify a witness [in the manner required by the Court under Rule 26], the party is not allowed to use that information or witness . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1); *see W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, No. CV 11-515-

LPS-CJB, 2015 WL 12806484, at *3 (D. Del. Sept. 25, 2015). Although the Federal Rules clearly contemplate the exclusion of untimely or improper expert disclosures (and the concomitant exclusion of expert testimony), the Third Circuit cautions that because "[t]he exclusion of critical evidence is an extreme sanction," it should not be imposed where an untimely or improper expert disclosure amounts to only a "slight deviation from pre-trial notice requirements" or occasions only "slight prejudice" to the movant. *In re Paoli R.R. Litig.*, 35 F.3d 717, 791–92 (3d Cir. 1994) (internal quotation marks and citations omitted).

c. Discussion

Almirall does not challenge the expert's qualifications or methods, its complaint relates to lack of notice of the expert's opinions. For the most part, the Court finds Almirall's arguments appear unavailing—the Court is inclined to believe the evidence should be heard to the extent it is relevant. However, the Court cannot assess the relevance of the proffered testimony in this context. Because this is a bench trial, the Court finds the plaintiff's contentions are less compelling. Let it suffice to say that testimony will be permitted only on a proper showing of relevance, foundation, and compliance with the Federal Rules of Evidence.

Also, only testimony and opinions properly disclosed in expert reports will be permitted. Almirall's challenges to purportedly undisclosed testimony may be based on an unduly narrow reading of the reports. The Court is inclined to believe that the testimony as it relates to claim 1 of the '219 patent is a natural outgrowth of his testimony on claim 14 of the parent application. It appears that Almirall had notice of

the gist of Dr. Amiji's testimony. Accordingly, the Court finds Almirall's motion in limine should be denied, without prejudice to reassertion via a timely objection at trial.

B. Taro's motions in limine:

1. Motion in Limine to Exclude Argument, Evidence or Testimony Relying on Plaintiff's Commercial Product to Prove Infringement

a. Parties' Contentions

Taro moves to preclude Almirall from presenting evidence arguments or opinions that compare the accused Taro ANDA product to Almirall's NDA No. 207154 and/or its commercial ACZONE Gel, 7.5% to prove infringement. It argues such comparison is contrary to precedent since the language of the asserted patent claims, and not the patent holder's commercial product, to define the inquiry.

In response, Almirall contends that Federal Circuit case law does not contain such a prohibition and argues that comparisons of Taro's ANDA product and ACZONE Gel 7.5% can be relevant to infringement. Almirall notes that Taro does not dispute that its product, ACZONE gel 7.5%, meets all the limitations of the asserted claims. It also contends that whether certain excipients can form part of the PVB when they are not separately and explicitly recited in the claims is a question of fact.

b. Law

When an alleged infringer files abbreviated new drug application (ANDA), the patentee bears burden of showing by preponderance of the evidence that what is to be sold will infringe. 35 U.S.C.A. § 271(e)(2). *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Generally, in deciding the issue of infringement, the trier of fact does not compare the defendant's accused product or method to the plaintiff's

commercial product or method. *Precision Fabrics Grp., Inc. v. Tietex Int'l, Ltd.*, No. 1:13-CV-645, 2016 WL 6839394, at *14 (M.D.N.C. Nov. 21, 2016) (noting that the Federal Circuit has advised caution in applying the doctrine of equivalents, reminding courts that it is the terms of the claims, and not the products themselves, that are the focus of the inquiry). Rather, the trier of fact compares the defendant's accused product or method to the claims of the patent when deciding infringement. *See Mahurkar v. C.R. Bard, Inc*., No. 92 C 4803, 1993 WL 259446, at *10 (N.D. Ill. July 6, 1993) (stating that under the doctrine of equivalents, a court considers infringement of a claim and of an equivalent to a limitation of the claim); *see also In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1378 (Fed. Cir. 2008) (noting district court correctly noted that that evidence regarding infringement must compare the claims to the accused product).

The inquiry under 35 U.S.C. § 271(e)(2) is a standard infringement test and "[t]he only difference . . . is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved." *Glaxo Grp. Ltd. v. Ranbaxy Pharm., Inc.*, 262 F.3d 1333, 1337–38 (Fed. Cir. 2001) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d at 1569). Thus, to determine whether an ANDA applicant's proposed product infringes the a patent, the court compares the ANDA described product to the asserted claims as construed. *Id*. In order to infringe, the proposed product must contain all the limitations recited in the patent holder's asserted claims either literally or under the doctrine of equivalents. *Id*.

However, Federal Circuit case law does not contain a blanket prohibition against comparing the accused product to a commercial embodiment. *Adams Respiratory*

Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1288 (Fed. Cir. 2010). The comparison of an accused product to a commercial embodiment is acceptable where the commercial embodiment meets all the claim limitations. *Id.*; *see also Glaxo Group Ltd. v. TorPharm*, 153 F.3d 1366, 1373 (Fed.Cir.1998). "When a commercial product meets all of the claim limitations, then a comparison to that product may support a finding of infringement." *Adams Respiratory Therapeutics*, 616 F.3d at 1289.

c. Discussion

The Court finds that Taro's motion should be denied. A comparison to the patentee's commercial product may be relevant to infringement on a proper showing. Taro's argument would have more force if a jury were involved and there was a danger of confusion, misunderstanding, or misapplication of the law. This is a trial to the court and the parties can be assured that the court will compare the ANDA described product to the asserted claims as construed, as required under Federal Circuit law. Accordingly, the court finds Taro's motion in limine should be denied.

2. *Daubert* Motion to Exclude Dr. Majella E. Lane from Offering the Opinion Taro's Thickening Agent is Equivalent to Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer

a. Parties' Contentions

Taro moves for an order precluding Dr. Lane from offering opinions that the thickening agent in Taro's product is equivalent to the missing claim element Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer ("A/SA").[4] The parties do not

[4] The parties do not dispute that Taro's product does not contain A/SA. Because the parties agree that Taro's ANDA described product does not literally infringe the asserted claims of the patent, the infringement claims depend on Dr. Lane's doctrine of equivalents analysis.

dispute that Taro's product does not contain A/SA. Taro challenges Dr. Lane's focus on Almirall's commercial product and argues that her conclusions are based on a conclusory analysis that fails to apply established principles.

Almirall asserts that Taro's arguments relate to the weight and not the admissibility of the evidence. It argues that Taro's position is contrary to the meaning of the term "comprising" and to the court's claim construction of the term polymeric viscosity builder.

b. Law

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597, the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." The rule requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d); *see generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741–46 (3d Cir. 2000) (noting the requirements of Rule 702 embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability and fit"). "[T]he language of Rule 702 requiring the expert to testify to scientific knowledge means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3rd Cir. 1994) (quoting *Daubert*, 509 U.S. at 590).

An expert's opinion on a legal conclusion "'is neither necessary nor controlling.'" *See* *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1313 (Fed. Cir. 2013) (quoting *Avia Grp. Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1564 (Fed.Cir.1988), abrogated on other grounds by *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008) (en banc)). That said, an expert's opinion may be relevant to the factual aspects of the analysis leading to that legal conclusion. *Id*. When an expert's methodology is sound, and the evidence relied upon is sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd,* 564 U.S. 91 (2011). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

"Infringement may be found under the doctrine of equivalents if every limitation of the asserted claim, or its 'equivalent,' is found in the accused subject matter, where an 'equivalent' differs from the claimed limitation only insubstantially." *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379 (Fed. Cir. 2006) (quoting *Ethicon Endo–Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998)). "An accused device that 'performs substantially the same function in substantially the same way to obtain the same result' as the patented invention may infringe under this doctrine." *Id.* (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). What constitutes equivalency must be determined

against the context of the patent, the prior art, and the particular circumstances of the case. *Graver Tank & Mfg. Co.*, 339 U.S. 609.

An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was. *Id*.; *see also Intendis GMBH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1362 (Fed. Cir. 2016) (stating "[the Federal Circuit has] held that "[w]hen the claims and specification of a patent are silent as to the result of a claim limitation, . . . we should turn to the ordinary skilled artisan'" (quoting *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1365 (Fed. Cir. 2007)). Moreover,

> A finding of equivalence is a determination of fact. Proof can be made in any form: through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art. Like any other issue of fact, final determination requires a balancing of credibility, persuasiveness and weight of evidence.

Id. at 609-10.

c. Discussion

The Court finds Taro's motion reflects a disagreement with Dr. Lane's conclusions. There is no challenge to her qualifications or methods. The Court agrees that Taro's criticisms go to the weight and not the admissibility of her opinions. Taro's concerns can be addressed in cross-examination. The Court finds Taro's motion in limine should be denied with respect to Dr. Lane's testimony.

3. Motion in Limine to Exclude Argument, Evidence or Testimony Relying on the Doctrine of Equivalence to Provide Infringement Because Plaintiff is Barred by the Doctrine of Ensnarement

a. Parties' Contentions

Taro moves to preclude Almirall from offering evidence or argument that Taro infringes the '219 patent under the doctrine of equivalents, arguing that the theory cannot be asserted if it will encompass or "ensnare" the prior art.

Almirall argues that Taro's motion is a thinly-veiled, impermissible motion for summary judgment, effectively seeking a merits-based ruling on an equitable defense.

b. Law

Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or "ensnare," the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009)(quoting *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 870 (Fed. Cir. 1985), *overruled in part on other grounds, Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (en banc). "[E]nsnarement and prosecution history estoppel, collectively, two policy oriented limitations" on the doctrine of equivalents,' . . . are 'applied as questions of law'" and limit the scope of equivalency that a patentee is allowed to assert. *Id*. (noting the limitation is imposed even if a jury has found equivalence as to each claim element). The ensnarement inquiry is separate and distinct from the jury's element-by-element equivalence analysis, and it has no bearing on the validity of the actual claims.

Ensnarement is one of the legal limitations on the application of the doctrine of equivalents that is to be "determined by the court either on a pretrial motion for partial

summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." *DePuy Spine, Inc.*, 567 F.3d at 1323. In the ensnarement context, a district court may hear expert testimony and consider other extrinsic evidence regarding: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations. *Id*. at 1324.

c. Discussion

The Court agrees that Taro's arguments cannot be addressed in the context of a motion in limine. Further development of the evidence on ensnarement is necessary. There are genuine issues of material fact on the issue. Accordingly, the Court finds the motion should be denied at this time without prejudice to reassertion in a properly supported motion at the close of evidence, at the end of trial, or in a posttrial motion.

4. Motion in Limine to Exclude Argument, Evidence or Testimony Relying on Plaintiff's Improper Lead Compound Obviousness Analysis

a. Parties' Contentions

Taro moves, pursuant to Federal Rules of Evidence 402 and 403, to preclude Almirall from relying on or presenting arguments or evidence on an improper obviousness analysis requiring the identification of a "lead compound" that a person of ordinary skill in the art ("POSA") would have used as a starting point. It argues this is not a compound case—it involves a method of treating acne and rosacea with a pharmaceutical composition containing dapsone. Taro contends that the lead compound framework does not apply to this case.

Almirall agrees that the lead compound framework does not apply because the claims of the '219 patent are not directed to a new pharmaceutical compound and do not necessitate consideration of whether prior art discloses a particular lead compound, the modification of which would have been obvious. It nevertheless urges the Court to deny Taro's motion, contending that evidence that a skilled artisan would not have obviously selected dapsone as the pharmaceutical agent in developing an improved treatment for acne or rosacea is relevant and admissible for determining whether Taro's obviousness analysis falls prey to hindsight bias. It argues it is prepared at trial to rebut Taro's invalidity with evidence that, in 2012, skilled artisans would have selected other drugs approved for acne or rosacea over dapsone in developing an improved treatment. It argues that it should be allowed to present evidence that shows that only hindsight bias would support a POSA's choice of dapsone to develop an improved treatment.

b. Law

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007). "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *KSR*, 550 U.S. at 406 (citation and quotation marks omitted). A court is required to consider secondary considerations,

or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F3d 1063, 1078–79 (Fed. Cir. 2012).

To show that a combination of elements is obvious, courts consider the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements. *KSR,* 550 U.S. at 421 (2007) (referring to so-called "TSM test"). The test should be flexibly applied. *Id.*; *see, e.g., DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006) ("Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense").

c. Discussion

The Court finds it is difficult to determine the relevance of the challenged evidence in the context of a pretrial motion. Evidence and argument regarding hindsight bias may be relevant, but the court cannot determine the parameters of such evidence at this time. The defendant's challenge is more in the nature of a objection to be raised at trial. Again, because this is a trial to the court, Taro's concerns are less compelling. The court finds the motion should be overruled at this time, without prejudice to reassertion at trial.

5. *Daubert* Motion to Exclude Dr. Julie Harper from Testifying About the Obviousness of the Asserted Claims of the '219 Patent

a. Parties' Contentions

Defendant Taro moves to exclude the testimony of Dr. Julie Harper on the obviousness of the asserted claims of the '219 patent. It asserts that Dr. Harper is not

qualified to render those opinions. Taro's arguments are based on its assertion that Dr. Harper is not a person of ordinary skill in the art ("POSA"), contending that Dr. Harper candidly testified she is not a POSA under the definition she provided in her expert report.

Almirall responds that Dr. Harper is a practicing board-certified dermatologist, with almost twenty years of experience and has conducted research, published, and presented extensively regarding both acne and rosacea treatment. It argues that the definitions of a POSA offered by both parties include "consultation or collaboration with" someone with Dr. Harper's expertise.[5] It also argues that during the prosecution of the '219 patent, the patent examiner defined a POSA as having a level of skill in the art of "high" and "at least that of a medical doctor with several years of experience in the art." (D.I. 133-2, Ex. 7) Almirall contends that Taro's motion ignores the parties' and the

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[5] The parties submit the following definitions of a POSA for the '219 patent. Taro proposes:

> A POSA for the '219 patent would have had at least a bachelor's degree, and more likely a master's or Ph.D., in pharmaceutical sciences or a related discipline; a minimum of three years' training or experience; and an understanding of drug-development. The more experience he or she had, the less formal education he or she would have needed. The POSA would have knowledge of topical dosage forms and formulations, including those containing dapsone, as well as thickening agents and other common excipients. He or she would have been aware of the prior art commercial and patent-protected dapsone gel formulations. Lastly, the POSA would have had at least a basic understanding of, or collaborated with others having, expertise in treating acne and/or rosacea.

(D.I. 133-1, Ex. 3, Taro Statement of Issues of Fact at 15-16) Almirall proposes:

> A POSA to which the '219 Patent pertains would have either: (i) a bachelor- or master-level degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus at least three years' experience in drug delivery, pharmaceutical formulations, or a related field; or (ii) a doctoral degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus some experience in drug delivery, pharmaceutical formulations, or a related field.

(D.I. 133-1, Ex. 2, Almirall's Statement of Issues of Fact at 29-30)

examiners' agreement that the perspective of a dermatological clinician is relevant to the claimed invention.

b. Law

The Third Circuit explains that "[q]ualification requires that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert as such." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003); *see also supra* at 10-11. An expert should not be excluded "simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (allowing an engineer to testify about the inadequacy of a warning in a service manual for an automotive rear liftgate, even though the expert was not substantively qualified in the design of automobile rear liftgates or the drafting of service manual warnings).

c. Discussion

Taro does not dispute that Dr. Harper's testimony is based on sufficient facts and data and she has reliably applied the principles and methods of the case. Dr. Harper possesses technical expertise on a relevant aspect of the pertinent art and the Court is satisfied that Dr. Harper's qualifications are sufficient to make her testimony helpful to an understanding of the evidence. The Court will permit Dr. Harper to offer testimony from a clinical perspective to rebut evidence of obviousness but will afford it the weight it deserves. To the extent her testimony is less credible or deserves less weight than that of a formulator, that is an issue for cross-examination. Again, Taro's concerns are

obviated by the fact that this is a trial to the Court. Accordingly, the Court finds the motion in limine to preclude Dr. Harper's testimony should be denied without prejudice to reassertion via a timely objection at trial.

IT IS ORDERED that the parties' motions in limine (D.I. 133-1, Ex. 13 and D.I. 133-2, Ex. 14) are granted in part and denied in part, as set forth above, without prejudice to reassertion at trial.

Dated this 24th day of January 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge